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(2)

No. 83-1537

In the Supreme Court of the United States

OCTOBER TERM, 1983

KATHLEEN HASLER AND MICHAEL HASLER,
PETITIONERS

v.

UNITED STATES OF AMERICA

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SIXTH CIRCUIT

MEMORANDUM FOR THE UNITED STATES IN OPPOSITION

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8 pp

TABLE OF AUTHORITIES

Cases:	Page
General Talking Pictures Corp. v. *Western Electric Co.*, 304 U.S. 175	6
Gicas v. *United States*, 508 F. Supp. 217	5
Hixenbaugh v. *United States*, 506 F. Supp. 461	4
Inwood Laboratories, Inc. v. *Ives Laboratories, Inc.*, 456 U.S. 844	5, 6
Kaminski v. *Grand Truck W.R.R.*, 347 Mich. 417, 79 N.W.2d 899	4
Smith v. *E.R. Squibb & Sons, Inc.*, 405 Mich. 79, 273 N.W.2d 476	2
Swin Flu Immunization Prods. Liab. Litigation, In re, 533 F. Supp. 586	4
Tabaczynski v. *United States*, 529 F. Supp. 156, aff'd, 711 F.2d 1059	4, 5
United States v. *United States Gypsum Co.*, 333 U.S. 364	5
Warner v. *United States*, 522 F. Supp. 87	5
Statute and rule:	
National Swine Flu Immunization Program Act of 1976, Pub. L. No. 94-380, 90 Stat. 1113 *et seq.*	1
Fed. R. Civ. P. 52(a)	5

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Petitioners contend that the court of appeals improperly applied the clearly-erroneous standard of review in reversing the district court's judgment awarding them damages under the National Swine Flu Immunization Program Act of 1976, Pub. L. No. 94-380, 90 Stat. 1113 *et seq.*

1. The Swine Flu Immunization Program was an effort by the federal government to prevent a potential influenza epidemic by immunizing the population

of the United States. Approximately 45 million Americans were vaccinated as part of this program. Pet. App. A3. Petitioner Kathleen Hasler [1] received a swine flu vaccination on November 24, 1976. Ten days later she began experiencing pain and stiffness in her joints and muscles, and developed a high fever and rash. Petitioner's treating physician diagnosed her condition at the time as a form of rheumatoid arthritis known as Still's Disease. Several months later, he changed his diagnosis to an acute rheumatoid-like condition secondary to the swine flu vaccination. *Id.* at A4.

Petitioners filed suit against the government in the United States District Court for the Eastern District of Michigan, alleging that her illness was caused by the vaccine and that the government was negligent in manufacturing and distributing the vaccine without adequate warnings or testing (Pet. App. A13, A20). After a bench trial, the court entered judgment in petitioners' favor totalling $1,550,000 (*id.* at A32). Although it did not address the foreseeability of the risk of rheumatoid arthritis resulting from the swine flu vaccine, or the need for a warning of such a risk, see *Smith* v. *E.R. Squibb & Sons, Inc.*, 405 Mich. 79, 273 N.W.2d 476 (1979), the district court concluded that the warnings given were inadequate (Pet. App. A24, A26). While characterizing the question of causation as the "most difficult" in the case, and "not * * * easily resolved," the court decided that petitioners had carried their burden of proof (*id.* at A26, A31). In reaching this conclusion, the court relied

[1] The other petitioner is Ms. Hasler's husband, who brought suit derivatively, claiming loss of consortium and of his wife's services (Pet. App. A13). For simplicity, "petitioner" will be used to refer to Ms. Hasler.

most heavily on "the temporal relationship—the sudden onset of the disease ten days after the swine flu shot," which, the court said, it could not regard as "mere coincidence" (*id.* at A31).

The court of appeals reversed on the ground that the district court's resolution of the causation question was clearly erroneous.[2] Pet. App. A5-A6. Addressing the temporal relationship between vaccination and onset of the disease, the court reasoned:

> Nearly 45 million Americans were inoculated against swine flu. It is not surprising that at least one of those 45 million persons should fall ill shortly after the shot was administered. Without more, this proximate temporal relationship will not support a finding of causation.

Id. at A7. The other factors relied on by the district court in making its inference of causation were also considered by the court of appeals and found inadequate.[3] The court of appeals concluded that "any

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[2] The court of appeals did not address any of the government's other contentions, which concerned the district court's treatment of certain warning issues and the amount of damages awarded.

[3] The district court noted that petitioner had previously been in good health and that some of her symptoms were not found in the "normal" case of Still's Disease (Pet. App. A31). The court of appeals, however, noted evidence in the record that these factors were not uncommon in Still's Disease (*id.* at A7-A8). The district court had also relied on the facts that the swine flu vaccine can cause an immunological "antigen-antibody" reaction and that rheumatoid arthritis can be related to such a reaction (*id.* at A30). The court of appeals disputed neither of these findings, but concluded that petitioner "failed to present any theory linking these facts to show

causal connection between the swine flu inoculation and the [petitioner's] rheumatoid arthritis [is] merely conjectural": while consistent with the facts, petitioner's explanation could not be reasonably or logically inferred from those facts (*id.* at A8-A9, A6). See *Kaminski* v. *Grand Truck W.R.R.*, 347 Mich. 417, 422, 79 N.W.2d 899, 901-902 (1956).

2. The decision of the court of appeals is manifestly correct and does not conflict with any decision of this Court or any other court of appeals. Moreover, the decision is intimately bound with the specific facts of the case. Further review by this Court therefore is not warranted.

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that her immunological reaction to swine flu caused the autoimmune disease from which she suffers" (*id.* at A8).

The court of appeals' analysis of this issue accords with that made in other swine flu cases. See, *e.g.*, *Tabaczynski* v. *United States*, 529 F. Supp. 156 (E.D. Mich. 1981), aff'd mem., 711 F.2d 1059 (6th Cir. 1983); *Hixenbaugh* v. *United States*, 506 F. Supp. 461 (N.D. Ohio 1980). As the court in *Tabaczynski* explained, it is not enough merely to posit an immunological theory of causation. There must be some showing that the same antibodies that are produced by the swine flu vaccine are also related to the disease in question, or at least some medical literature suggesting an association between the vaccine and the disease. 529 F. Supp. at 159, 162. Here, as in *Tabaczynski*, such evidence was wholly lacking. Pet. App. A8; see also C.A. App. 171, 191, 903. Moreover, one of petitioners' own experts, Dr. Sliwinski, admitted that there has been no evidence of an increased incidence of rheumatoid arthritis following the swine flu program (C.A. App. 904). Absence of a greater prevalence of a disease following the 45 million inoculations given as part of the swine flu program has been deemed revelant to the determination that no causal relation exists between vaccination and the disease. *In re Swine Flu Immunization Prods. Liab. Litigation*, 533 F. Supp. 586, 593 (D. Colo. 1981).

a. The court of appeals explicitly stated and relied on the clearly-erroneous standard of review mandated by Rule 52(a) of the Federal Rules of Civil Procedure and explained in *United States* v. *United States Gypsum Co.*, 333 U.S. 364, 395 (1948) (Pet. App. A5-A6). Cf. *Inwood Laboratories, Inc.* v. *Ives Laboratories, Inc.*, 456 U.S. 844 (1982) (court of appeals failed to apply Rule 52(a)). The court of appeals properly applied this standard, giving due deference to the findings of the district court. It did not substitute its own judgments of credibility. Rather, it simply determined that, on the evidence presented to the district court, any inference of causation would of necessity be "mere conjecture" (Pet. App. A6). In this the court of appeals was undoubtedly correct. See, *e.g.*, *Warner* v. *United States*, 522 F. Supp. 87, 89-90 (M.D. Fla. 1981) (plaintiff's theory of causation based largely on the temporal relation between swine flu inoculation and injury was "purely speculative"); *Tabaczynski* v. *United States*, 529 F. Supp. 156 (E.D. Mich. 1981), aff'd mem., 711 F.2d 1059 (6th Cir. 1983) (temporal relation insufficient to establish causation in swine flu case); *Gicas* v. *United States*, 508 F. Supp. 217 (E.D. Wis. 1981) (plaintiff failed to establish that joint disease was caused by swine flu vaccine). Contrary to petitioners' assertion, the court of appeals has not endorsed de novo appellate review of facts.[4]

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[4] Petitioners' other contention, that the court of appeals required a higher standard of proof than a preponderance of the evidence, is frivolous. Nowhere does the court require a plaintiff "to establish medical causation absolutely" or "beyond a reasonable doubt" (Pet. 21). To the contrary, the court of appeals held that petitioners' proof of causation did not rise above the level of conjecture. A more refined weighing of probabilities was therefore not pursued. The court's passing

b. A reading of the court of appeals' opinion demonstrates that its significance extends little beyond the parties to this particular action. It creates no new law, nor relies on any legal proposition that has not been long and firmly established. A writ of certiorari "would not be warranted merely to review the evidence or inferences drawn from it." *General Talking Pictures Corp.* v. *Western Electric Co.*, 304 U.S. 175, 178 (1938). Whether or not a district court's factual findings are clearly erroneous "is a question best decided by the courts of appeals, who have a good deal more experience with the application of this principle" than does this Court. *Inwood Laboratories, Inc.* v. *Ives Laboratories, Inc.*, 456 U.S. at 864 (Rehnquist, J., concurring in the result). Further review is unwarranted where, as here, the issue is "whether the clearly-erroneous standard, although properly invoked, was erroneously applied." *Id.* at 859 (White, J., concurring in the result).

It is therefore respectfully submitted that the petition for a writ of certiorari should be denied.

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JUNE 1984

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use of the phrase "with certainty" in connection with the basic facts shown by the evidence obviously was not intended to change the burden of proof in civil cases in general or this one in particular (Pet. App. A8).

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